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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,789	11/19/2003	Richard J. Davies	DAVIES 3.0-001 CIP II	6132
530	7590	12/29/2005	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			DRYDEN, MATTHEW DUTTON	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,789

Applicant(s)

DAVIES, RICHARD J.

Examiner

Matthew D. Dryden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/31/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/19/2004, 8/16/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and method, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 31, 2005.

Applicant's election without traverse of claims 32-41 in the reply filed on October 31, 2005 is acknowledged.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first device operative to display the first electrophysiological characteristic and a second device operative to display the second electrophysiological characteristic must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

A new abstract should be submitted disclosing only the invention that remains in the elected claims, and should not refer to the invention of the nonelected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Long, Jr. et al (5697369).

Regarding claim 32, Long, Jr. et al discloses a method for disease, injury and bodily condition screening or sensing comprising the steps of:

measuring a first electrophysiological characteristic of an area of tissue to be treated (see Column 10, lines 6-8),

applying a treatment to the area of tissue (see Column 9-10, lines 65-4),

measuring a second characteristic (see Column 10, lines 6-22),

comparing the two characteristics (see Column 10, lines 4-11),

determining the efficacy (see Columns 9-10, lines 62-14).

Regarding claim 33, the therapy discussed in the patent to Long, Jr. et al is radiation therapy (see Column 9, lines 65-67).

Regarding claim 34, Long, Jr. et al disclose:

applying a treatment to an area of tissue (Columns 9-10, lines 62-4),

measuring an electrophysiological characteristic and comparing the values to initial levels, which can be viewed as pre-determined values (Column 10, lines 6-11),

determining the efficacy of the treatment, (see Columns 9-10, lines 62-14).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 40 is rejected under 35 U.S.C. 102(e) as being anticipated by Kaiser (6363275). Kaiser teaches a device for detecting and characterizing tissues that includes two electrodes (elements 12 and 13 in Figure 1), that produce two separate signals and are viewed as two separate electrophysiological characteristics, and each electrode is capable of measuring a characteristic of an area of tissue to be treated and an area of normal tissue. Kaiser also teaches a device operative to determine the difference between the characteristics (see column 2, lines 6-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Long, Jr. et al in view of Organ (6122544). Long, Jr. et al discloses the claimed method steps except for determining an electrophysiological characteristic of a second area of tissue that was comprised of normal tissue. Organ discloses a method for detecting and diagnosing diseases that teaches it is known to take impedance measurements of a diseased tissue site and a normal tissue site and to compare the values accordingly (see Column 2, lines 46-60), to provide a good control for determining the efficacy of the treatment method and also allows for the condition to be tracked over an extended period of time. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Long, Jr. et al with a step of testing to separate areas of tissue one of which can be diseased and the other is normal tissue, as taught by Organ, to provide a good control for determining the efficacy of the treatment method and also allows for the condition to be tracked over an extended period of time.

Regarding claim 37, although not specifically taught by Organ it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method steps of Long, Jr. et al as modified with a step of measuring the area of a normal tissue near the tissue to be treated to provide a more accurate analysis of the tissue because the closer the normal tissue is to the treated to tissue the more it would exemplify the normal characteristics.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Long, Jr. et al in view of Organ as applied to claim 35 above, and further in view of Kaiser. Long, Jr. et al as modified discloses the claimed method steps except for an agent being introduced into the area of tissue being treated. Kaiser teaches a device for detecting and characterizing tumors that includes introducing an agent into the area of tissue to be treated (see Column 2, lines 56-67), to increase the accuracy of the measurements taken from the desired tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device of Long, Jr. et al with a method step of introducing an agent into the desired tissue area, as taught by Kaiser, to increase the accuracy of the measurements taken from the desired tissue.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaiser in view of Jordan (6823203). Kaiser discloses the claimed invention except for the device having multiple output devices for each electrode. Jordan discloses a system and method for diagnostic systems that includes multiple output devices for display (see Figure 1, around elements 18 and 20 and see Figure 4 around elements 412), which would be capable of displaying a first electrophysiological characteristic on one monitor, and another electrophysiological characteristic on a different monitor. The purpose of providing separate display devices is to allow the user of the system to track each electrophysiological characteristic independently. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Kaiser with multiple display devices for displaying two electrophysiological

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characteristics, as taught by Jordan, to allow the user of the system to track each electrophysiological characteristic independently.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Long, Jr. et al in view of Organ as applied to claim 36 above, and further in view of Armato, III et al (6898303). Long, Jr. et al as modified discloses the claimed method steps but does not disclose the method being on a computer-readable medium. Armato, III et al teaches that it is known to provide a detection of lesions in a tissue on a computer-readable medium (see Columns 5-6, lines 65-3), in order to make the procedure more streamlined and accurate for the user of the system. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device and method of Long, Jr. et al with a computer-readable medium for performing the method steps, as taught by Armato, III et al, to make the procedure more consistent, repetitive, and accurate for the user of the system.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 6,496,725 Kamada et al discloses an apparatus for determining degree of restoration of diseased part

U.S. Pat. No. 5,810,742 Pearlman discloses a tissue characterization based on impedance images and on impedance measurements

U.S. Pat. No. 6,026,322 Korenman et al discloses a biofeedback apparatus for use in therapy

U.S. Pat. No. 6,389,305 Dehan et al discloses a method and apparatus for detection of cancerous and precancerous conditions in a breast.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD


MAX F. HINDENBURG
SUPERVISOR PATENT EXAMINER
ELECTRONIC BUSINESS CENTER 3736